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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,901	01/26/2001	Joaquina Faour	PHUS-28	7749

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/770,901	Applicant(s) FAOUR ET AL.	
	Examiner Shaojia A Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8,10-38 and 40-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-8, 10-38 and 40-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on October 23, 2003 wherein claims 1, 4-8, 10-38 and 40-54 have been amended and claims 2-3, 9, and 39 are cancelled; wherein the specification has been amended as to page 42.

Currently, claims 1, 4-8, 10-38 and 40-54 are pending in this application.

Claims 1, 4-8, 10-38 and 40-54 as amended now are examined on the merits herein.

Applicant's second supplemental declaration of Ethel C. Feleder (not inventor) under 37 C.F.R. 1.132 filed on October 23, 2003 under 37 CFR 1.132, are acknowledged and will be further discussed below.

Applicant's remarks and Exhibits filed on October 23, 2003 and Attachments A-D filed on September 23, 2002 in Paper No. 18 with respect to the rejection of claims 7-8, 12, 14, 16-18, 22-23, 28-29, 31-37, 43-45 and 52-54 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expressions, i.e., "slow or rapid release", for example, in claim 12, "rapidly", for example, in claim 18, "rapid, immediate.. slow, timed, target, pseudo-first order, ...second order and/or delayed release..", for example, in claim 29, and "rapid release" or "a delayed but rapid release" in claims 31-37, renders claims 7-8, 12, 14, 16-18, 22-23, 28-29, 31-37, 43-45 and 52-54 indefinite. The expressions "slow or rapid release", "rapidly", "rapid, immediate.. slow, timed, target, pseudo-first order, ...second order and/or delayed release..", and "rapid release" or "a

delayed but rapid release" of record stated in the Office Action dated April 23, 2003 have been fully considered and found persuasive to remove the rejection since these terms or expressions have been known and used in the art. Therefore, the said rejection is withdrawn.

Applicant's amendment filed on October 23, 2003 with respect to the rejection of Claims 7-8, 16-17, and 40-48 for containing the trademark/trade name, e.g., SC-5766, SC-58215, and T-614 of record stated in the Office Action dated April 23, 2003 have been fully considered and found persuasive to remove the rejection since these terms or expressions have been removed from the claims. Therefore, the said rejection is withdrawn.

The following are new rejection(s) necessitated by Applicant's amendment filed on October 23, 2003, wherein the recitations and limitations in the amended claims have been changed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-5, 10, 13-14, and 18-38, and claims 8, 17, and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in

the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment submitted October 23, 2003 with respect to amended claims 1, 10, and 40 has been fully considered but is deemed to insert new matter i.e., reciting "wherein inhibitor binds COX-II receptors selectively over COX-I receptors or binds COX-II receptors specifically" and "..providing an additive or synergistic therapeutic effect", into the claims since nowhere can these recitations "wherein inhibitor binds COX-II receptors selectively over COX-I receptors or binds COX-II receptors specifically" and "..providing an additive or synergistic therapeutic effect"., be found in the originally filed specification or the specification as originally filed does not provide support these recitations.

Applicant's amendment submitted October 23, 2003 with respect to amended claims 12, 29, 34, 36, and 52-53 has been fully considered but is deemed to insert new matter i.e., reciting "release at a faster rate than the muscle" and "..released at a slower", into the claims since nowhere can these recitations be found in the originally filed specification or the specification as originally filed does not provide support these recitations.

Applicant's amendment submitted October 23, 2003 with respect to amended claims 8, 17, and 40 has been fully considered but is deemed to insert new matter i.e., reciting chemical names for NS-398, DUP-697, SC-57666, and T-614, into the claims since the specification as originally filed does not provide support for chemical names

for NS-398, DUP-697, SC-57666, and T-614. The original specification does not disclose chemical names for NS-398, DUP-697, SC-57666, and T-614.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Applicant is suggested to provide a proof (e.g., journal articles or patents or literatures) for the identification for these names recited in the claims for NS-398, DUP-697, SC-57666, and T-614.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-5, 10, 13-14, and 18-38 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular COX-II inhibitors and the particular muscle relaxants disclosed in the specification (i.e., claims 40 and 49) in composition herein, does not reasonably provide enablement for the employment any COX-II inhibitors wherein inhibitor binds COX-II receptors selectively over COX-I receptors or binds COX-II receptors specifically and any muscle relaxants recited in the claims herein, for the same reasons of record in the previous Office Action April 23, 2003.

These recitations, "a COX-II inhibitor wherein inhibitor binds COX-II receptors selectively over COX-I receptors or binds COX-II receptors specifically" and "a muscle relaxant", are seen to be merely functional language.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to pharmaceutical compositions for the particular treatments.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since the broadest claim (i.e., claims 1 and 10) reads on any COX-II inhibitor wherein inhibitor binds COX-II receptors selectively over COX-I receptors or binds COX-II receptors specifically and any muscle relaxant employed in the composition herein.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". The CAFC further clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405(emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphasis added).

In the instant case, the phrase "a COX-II inhibitor wherein inhibitor binds COX-II receptors selectively over COX-I receptors or binds COX-II receptors specifically" and "a muscle relaxant" in claims herein, recited in the instant claims are purely functional distinction. Hence, these functional recitations read on any compounds that might have the recited functions. However, the specification merely provides particular COX-II inhibitors and particular muscle relaxants for the composition in claims 40 and 49. The predictability or unpredictability: the instant claimed invention is highly *unpredictable* as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California v. Eli Lilly and Co.* Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art is unable to fully predict possible physiological activities of any compounds having claimed functional properties in the pharmaceutical compositions herein.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, side effects, and especially serious toxicity that may be generated by drug-drug interactions when and/or after administering to a host the ***combination*** of any compounds represented by "a COX-II inhibitor wherein inhibitor binds COX-II receptors selectively over COX-I receptors or binds COX-II receptors specifically" and "a muscle relaxant", which might encompass more than a hundred compounds. See text book "Goodman & Gilman's The Pharmacological Basis of Therapeutics" regarding possible drug-drug interactions (9^{th} ed, 1996) page 51 in particular. This book teaches that "The frequency of significant beneficial or adverse drug interactions is unknown" (see the bottom of the left column of page 51) and that "Recognition of beneficial effects and recognition of and prevention of adverse drug

interactions require a thorough knowledge of the intended and possible effects of drugs that are prescribed" and that "The most important adverse drug-drug interactions occur with drugs that have serious toxicity and a low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences" (see the right column of page 51) (emphases added). In the instant case, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art is unable to fully predict possible adverse drug-drug interactions occurring with many combinations of any compounds having claimed functional properties in the pharmaceutical compositions herein to be administered to a host. Thus, the teachings of the book clearly support that the instant claimed invention is highly unpredictable.

The presence or absence of working examples and the quantity of experimentation necessary:

As discussed above, only those particular compounds for each kind of functional compounds employed in the compositions of Examples 1-13 are disclosed in the specification. It is noted in the supplemental declaration of Ethel C. Feleder under 37 C.F.R. 1.132 filed on October 23, 2003, that only two combinations, i.e., rofecoxib (a COX-II inhibitor) and pridinol (a muscle relaxant); diclofenac and pridinol, were tested to be administered to a host. Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the active agents or compounds in the claimed composition. See MPEP § 716.02(d).

Thus, the specification fails to provide sufficient support of the **broad** use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

Therefore, in view of the *Wands* factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation* to test all compounds encompassed in the instant claims and their combinations employed in the claimed compositions to be administered to a host, with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to the employment of a pharmaceutical composition comprising a combination of active agents herein having "synergistic therapeutic effect".

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to pharmaceutical compositions for the particular treatments.

The relative skill of those in the art: The relative skill of those in the art is high.

In regard to the following *Wands* factors, the predictability or unpredictability of the art; the amount of direction or guidance presented; the presence or absence of working examples as discussed below:

The instant claimed invention is highly *unpredictable*. Synergistic or superadditive effects for combinations of compounds are highly unpredictable. In the instant case there is insufficient guidance and **no** working examples in the specification showing that the particular agents in specific amounts to be combined achieved synergistic effects in the particular treatment. As discussed above, it is noted in the supplemental declaration of Ethel C. Feleder under 37 C.F.R. 1.132 filed on October 23, 2003, that only two

combinations, i.e., rofecoxib (a COX-II inhibitor) and pridinol (a muscle relaxant); diclofenac and pridinol, were tested to be administered to a host and showing additive or less than additive effect (see Table 1 and 2 in Exhibit A & B of the supplemental declaration). Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the active agents or compounds in the claimed composition. See MPEP § 716.02(d).Thus, the specification fails to demonstrate any synergistic effects produced by any combinations herein.

Therefore, in view of the *Wands* factors discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation* to test all compounds encompassed in the instant claims whether they produced a synergistic effect in treating erectile dysfunction, with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 29, 34, 36, and 52-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, of record in the previous Office Actions dated April 9, 2002 and September 28, 2001.

The expressions reciting "release at a faster rate than the muscle" and "..released at a slower..", for example, renders these claims indefinite. The expressions "faster", "slower" are not clear defined by the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-8, 10-38 and 40-54 as amended now are rejected under 35 U.S.C. 103(a) as being unpatentable over Burch et al. (WO 99/13799, of record) in view of Okada et al. (5,476,663, of record) for the same reasons of record stated in the Office Action dated April 23, 2003.

Burch et al. discloses that COX-II inhibitors such as rofecoxib (VIOXX or MK-966) are known to be useful in a composition and a method of treating pain. Burch et al. discloses that the composition therein comprising a COX-II inhibitor can also be combined with other active agents, e.g., other analgesic agents, or pharmaceutical expcipients, e.g., colorant and flavorant. Burch et al. further discloses various dosage forms, e.g., tablet, capsules and gelcaps that may control release of the active ingredients therein. See title and abstract, page 5 lines 7-8, page 13 lines 25-27, page 14 lines 4 and 23-30, page 23 and claim 10.

The prior art does not expressly disclose that the employment of the particular COX-II inhibitor such as rofecoxib in combination with the particular muscle relaxant such as pridinol in a pharmaceutical composition or dosage. The prior art does also not expressly disclose the effective amounts of active agents in the composition herein to be administered, e.g., the weight ratio of the COX-II inhibitor and the muscle relaxant.

Okada et al. teaches that a muscle relaxant such as pridinol is useful in combination with analgesic and/or antiinfammatory drugs (see col.3 lines 13-28).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a COX-II inhibitor such as rofecoxib in combination with a muscle relaxant such as pridinol in a pharmaceutical composition or dosage, and to optimize the effective amounts of active agents in the composition herein to be administered, e.g., the weight ratio of a COX-II inhibitor and a muscle relaxant.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a COX-II inhibitor such as rofecoxib in combination with a muscle relaxant such as pridinol in a pharmaceutical composition or dosage since COX-II inhibitors such as rofecoxib are known to be useful in a composition or dosage and a method of treating pain. Moreover, muscle relaxants such as pridinol are well known to be useful alone or in combination with conventional analgesics for the treatment of pain. Therefore, one of ordinary skill in the art would have reasonably expected that combining a COX-II inhibitor such as rofecoxib and a muscle relaxant such as pridinol known useful for the same purpose in a composition to be administered would improve the therapeutic effect for treating pain. Additionally, one of ordinary skill

in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the optimization of known amounts of known active agents to be administered is considered well within the skill of artisan.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Since all active composition components herein are known to useful to treat pain, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed on January 24, 2002 in Paper No. 10 and the supplemental declaration of Ethel C. Feleder under 37 C.F.R. 1.132 filed on October 23, 2003 with respect to this rejection of claims 1-8, 10-38, and 40-54 made under 35 U.S.C. 103(a) over Burch et al. have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

As discussed above, only those particular compounds for each kind of functional compounds employed in the compositions of Examples 1-13 are disclosed in the specification. It is noted in the supplemental declaration of Ethel C. Feleder under 37

C.F.R. 1.132 filed on October 23, 2003, that only two combinations, i.e., rofecoxib (a COX-II inhibitor) and pridinol (a muscle relaxant); diclofenac and pridinol, were tested to be administered to a host. Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the active agents or compounds in the claimed composition. See MPEP § 716.02(d).

Thus, the specification fails to provide sufficient support of the **broad** use of any combinations encompassed by the instant claims.

Nevertheless, the record contains no clear and convincing evidence of unexpected results or unexpected synergistic analgesic effect produced by any combinations herein over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a).

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

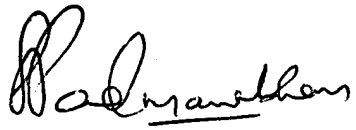
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. A. Jiang, Ph.D.
Patent Examiner, AU 1617
December 30, 2003



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

1/12/04